K093213

MAR 12 2010

5. 510(K) SUMMARY

510(k) SUMMARY
Guided Progression Analysis (GPA)
for the Humphrey® Field Analyzer II and II – *i* series

GENERAL INFORMATION

Manufacturer:	Carl Zeiss Meditec Inc. 5160 Hacienda Drive Dublin, California 94568 (925) 557-4616 (phone) (925) 557-4259 (fax) Est. Reg. No. 2918630
Contact Person:	Judith A. Brimacombe, MA Director, Regulatory/Clinical Affairs Carl Zeiss Meditec Inc. 5160 Hacienda Drive Dublin, California 94568 (925) 557-4616 (phone) (925) 557-4259 (fax)
Classification name:	Perimeter
Classification:	Class I (according to 21 CFR 886.1605)
Product Code:	HPT
Trade/Proprietary name:	Guided Progression Analysis (GPA) for the Humphrey® Field Analyzer II and Humphrey® Field Analyzer II – *i* series

PREDICATE DEVICES

Company: Device:	Carl Zeiss Meditec, Inc. Humphrey® Field Analyzer II (K954167)
Company: Device:	Carl Zeiss Meditec, Inc. Cirrus™ HD-OCT with Retinal Nerve Fiber Layer and Macular Normative Databases (K083291)

K093213

INTENDED USE

The Guided Progression Analysis for the Humphrey® Field Analyzer II (HFA II) and Humphrey® Field Analyzer II- *i* series is a software analysis module that is intended for use as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, glaucoma. It is also intended to compare change over time and determine if statistically significant change has occurred.

INDICATIONS FOR USE

The Carl Zeiss Meditec, Inc. Guided Progression Analysis is a software analysis module for the Humphrey® Field Analyzer II (HFA II) and Humphrey® Field Analyzer II - *i* series (HFA II – *i*) that assists practitioners with the detection, measurement, and management of progression of visual field loss. It aids in assessing change over time, including change from baseline and rate of change. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, glaucoma.

DEVICE DESCRIPTION

The Carl Zeiss Meditec, Inc. Guided Progression Analysis (GPA) is a software package for the Humphrey Field Analyzer II and II - i series that is designed to help practitioners identify progressive visual field loss in glaucoma patients. GPA compares the visual field test results of up to 14 follow-up tests to an established baseline over time and determines if there is statistically significant change. The GPA printout highlights any changes from baseline that represent larger than expected clinical variability, and it provides simple plain-language messages such as "Possible Progression" or "Likely Progression" whenever changes show consistent and statistically significant loss. The GPA printout also presents the Visual Field Index (VFI), a global index which reports a measure of the patient's remaining useful vision in the form of a percentage, as well as the VFI Rate of Progression plot which provides a trend analysis of the patient's overall visual field history and indicates a 3-5 year projection of the VFI regression line if the current trend continued.

SUBSTANTIAL EQUIVALENCE

The Guided Progression Analysis for the Humphrey® Field Analyzer II (HFA II) and Humphrey® Field Analyzer II- *i* series is substantially equivalent to the Humphrey® Field Analyzer II and Guided Progression Analysis for the Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL) and Macular Normative Databases. The

indications for use for the Guided Progression Analysis for the Humphrey® Field Analyzer II and Humphrey® Field Analyzer II- *i* series are similar to the indications for the predicate devices cited in this application. A technological comparison demonstrates that the Guided Progression Analysis for the Humphrey® Field Analyzer II (HFA II) and Humphrey® Field Analyzer II- *i* series is functionally equivalent to the predicate devices.

Evaluation of published literature on Guided Progression Analysis for the Humphrey® Field Analyzer II and Humphrey® Field Analyzer II- *i* series supports the indications for use statement, and demonstrates that the device is substantially equivalent to the predicate devices and does not raise new questions regarding safety and effectiveness.

CLINICAL EVALUATION

Clinical data on GPA has been collected by various researchers and is reported in the clinical literature.[1,2] A review of the clinical literature that discusses the relevant studies related to the development of GPA for analysis of visual field progression has been included in this Premarket Notification. GPA incorporated the visual field progression metrics successfully used in the Early Manifest Glaucoma Trial (EMGT),[3,4] in which pattern deviation maps were used to identify statistically significant visual field progression.

Carl Zeiss Meditec, Inc. sponsored a study to quantify perimetric test-retest variability in glaucoma subjects having a wide range of visual field loss. A total of 363 qualified glaucoma subjects were enrolled across a worldwide nine-site study. Each subject was tested four times within one month. The results of this study, which used the three threshold testing algorithms available on the Humphrey Field Analyzer (SITA Standard, SITA Fast, and Full Threshold), established the limits for change at different significance levels based on test-retest variability in glaucomatous visual fields. The results allow HFA GPA to indicate when the change for a given patient at a given test location exceeds the test-retest variability for the region.

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1 Arnalich-Montiel F, Casas-Llera P, Muñoz-Negrete FJ, Rebolleda G. Performance of glaucoma progression analysis software in a glaucoma population. Graefes Arch Clin Exp Ophthalmol 2009;247:391–397.

2 Casas-Llera P, Rebolleda G, Muñoz-Negrete FJ, Arnalich-Montiel F, Pérez-López M, Fernández-Buenaga R. Visual field index rate and event-based glaucoma progression analysis: Comparison in a glaucoma population. *Br. J. Ophthalmol.* published online 16 Jun 2009.

3 Leske CM, Heijl A, Hyman L, Bengtsson B for the Early Manifest Glaucoma Trial Group. Early Manifest Glaucoma Trial - Design and baseline data. *Ophthalmology* 1999;106:2144 –2153.

4 Heijl A, Leske CM, Bengtsson B, Hyman L, Bengtsson B, Hussein M for the Early Manifest Glaucoma Trial Group. Reduction of intraocular pressure and glaucoma progression - results from the Early Manifest Glaucoma Trial. *Arch Ophthalmol.* 2002;120:1268-1279.

GPA was further refined to include the visual field index (VFI) described by Bengtsson and Heijl.[5] This index utilizes data from the pattern deviation probability maps and is incorporated into the new VFI graphical analysis in the GPA software. Linear regression analysis was used to determine the rate of change in VFI. For a visual field series with sufficient follow-up data, the linear regression line is extended into the future to aid the clinician in estimating a patient's future visual status, should previously observed progression rates continue into the future.

SUMMARY

As described in this 510(k) Summary, all testing deemed necessary was conducted on the Guided Progression Analysis for the Humphrey® Field Analyzer II (HFA II) and Humphrey® Field Analyzer II- *i* series to ensure that the device is substantially equivalent to the predicate devices, and safe and effective when used in accordance with its Instructions for Use.

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5 B. Bengtsson and A. Heijl. A visual field index for calculation of glaucoma rate of progression; Am J Ophthalmol, Feb 2008; 145(2): 343-53.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

MAR 12 2010

Carl Zeiss Meditec, Inc.
c/o Ms. Judith A. Brimacombe, M.A.
Director, Clinical and Regulatory Affairs
5160 Hacienda Drive
Dublin, CA 94568

Re: K093213
Trade/Device Name: Guided Progression Analysis (GPA) for the Humphrey® Field Analyser II and Humphrey® Field Analyser II – *i* series
Regulation Number: 21 CFR 886.1605
Regulation Name: Perimeter
Regulatory Class: Class II
Product Code: HPT
Dated: February 5, 2010
Received: February 12, 2010

Dear Ms. Brimacombe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K093213

Device Name: Guided Progression Analysis (GPA) for the Humphrey® Field Analyzer II and Humphrey® Field Analyzer II – *i* series

Indications for Use:

The Carl Zeiss Meditec, Inc. Guided Progression Analysis is a software analysis module for the Humphrey® Field Analyzer II (HFA II) and Humphrey® Field Analyzer II- *i* series (HFA II – *i*) that assists practitioners with the detection, measurement, and management of progression of visual field loss. It aids in assessing change over time, including change from baseline and rate of change. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, glaucoma.

Prescription Use _x_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

Bruce Drum

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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